

Application No. 09/376,794
Applicants: Rainer Kropke et al.
Amendment in Response to Office Action dated May 7, 2003

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claims 18-26 are pending. New claims 24-26 have been added. Support for new claims 24-26 is found in the specification at page 29 in the bottom example showing a comparison of the formulations when read in light the specification starting at page 2, lines 34-35 to page 3, lines 1-2. It is believed that no new matter has been added.

Rejections under 35 U.S.C. 103

The Examiner rejected claims 18-23 under 35 U.S.C. 103(a) as being obvious in view of EP 0 771 566 or Magdassi et al. (U.S. Patent No. 5,518,736) or FR 2,667,072 in view of Jordan (U.S. Patent No. 5,885,617).

The Examiner also rejected the claims as being obvious over EP 0 771 566 or Magdassi et al. or FR 2,667,072 in view of JP 63211208 and JP 03074316, further in view of Jordan.

The Examiner found each one of EP 0 771 566, Magdassi, and FR 2,667,072 to teach an emulsion containing chitosan and a phospholipids, but concedes that none of the references teach phospholipids to reduce tackiness. According to the Examiner, the JP references teach a phospholipid containing cosmetic compositions are non-sticky. The Examiner cited Jordan to

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show lecithin to be a known anti-tack agent. The Examiner ultimately found it would have been obvious to a person skilled in the art that lecithin would reduce the tackiness of the composition.

In response, Applicants submit the references have been improperly combined because Jordan is nonanalogous art. In order to rely on a reference as a basis for a rejection, (1) the reference must be in the "same field of endeavor", and (2) if the reference is not within the same field of endeavor, whether the reference is still reasonably pertinent to the particular problem involved. See MPEP §2141.01(a); See also *In re Clay*, 23 USPQ2d 1058 (Fed. Cir. 1992). As to (1), Jordan and the instant application are not in the same field of endeavor as Jordan is directed to a coating for pharmaceutical tablets while the instant application is directed to a method for reducing the tackiness of a composition to skin. Turning to (2), the Federal Circuit noted in *In re Clay*:

[T]he purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve...If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

23 USPQ2d at 1061. Applicants submit both Jordan and the instant application are directed to a different purpose. Jordan is directed to a coating for pharmaceutical tablets "which reduce the rate at which the dosage form absorbs atmospheric pressure." See Jordan, column 1,

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lines 28-29. In contrast, the instant claims are directed to a method for reducing tackiness of a composition to skin. Jordan, while acknowledging lecithin as an anti-tack agent, employs lecithin to overcome the problem of selecting a plasticizer in the context of pharmaceutical tablets. See Jordan, column 1, lines 47-50, and column 2, lines 51-55. The instant application employs a phospholipid, lecithin being one example, to reduce the tackiness of a composition comprising chitosan. Accordingly, Jordan is not in the same field of endeavor, nor does it address the same problem solved by the present invention. Therefore, Jordan is not analogous art, and not properly relied upon to support the present rejection.

Even if the references are combinable, which the Applicants do not concede, Applicants believe the Examiner, at best, has made out a *prima facie* case for obviousness. However, Applicants refer the Examiner to new claims 24-26 which claim a method of incorporating chitosan and a phospholipid into a preparation to reduce tackiness to skin while at the same time improving the stability of the preparation. Applicants have unexpectedly shown that when a phospholipid is combined with a chitosan, no such instability in the preparation was observed. This is demonstrated by the instant example found at the bottom of page 29 of the specification, wherein 3 separate formulations are presented: one with only chitosan; one with only a phospholipid; one with both chitosan and a phospholipid. Only the formulation having both chitosan and a phospholipid is stable, and when read in light of the specification at page 2, lines 34-35 to page 3, lines 1-2, the purposes of reducing tackiness and improving stability are achieved by the claimed method upon overcoming the problems of an alteration in viscosity and a reduction in stability when constituents such as talc were added in previous efforts to reduce

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the tackiness. Applicants submit the result showing both a reduction in tackiness and an improvement in the stability are unexpected, and the data in the example at the bottom of page 29 of the specification as objective evidence of nonobviousness. See MPEP §716.01(a). Consequently, even if the references could be combined and even if the references made out a *prima facie* case of obviousness for a reduction in tackiness of a composition to skin, there is still nothing to suggest to a person skilled in the art a phospholipid as combined with chitosan demonstrate a reduction in tackiness of the composition to skin, while at the same time improving the stability of the preparation.

Applicants believe the data supports the nonobviousness of claims 18-26. Even if the Examiner disagrees, Applicants certainly believes the data supports the nonobviousness of new claims 24-26, wherein nothing in the cited references suggest a method of incorporating chitosan and a phospholipid into a preparation to reduce tackiness to skin while at the same time improving the stability of the preparation.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw these rejections. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Conclusion

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

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Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (9 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: *November 7, 2003*

By



David D. Kim